



Certificate No. 6387-3-2023

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 15, 2023 to March 14, 2025.





U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Corporate Headquarters

DEFIBTECH, LLC
741 BOSTON POST ROAD
SUITE 201
Guilford, CT
USA 06437

Name of Manufacturer

Manufacturer

Legal Manufacturer

DEFIBTECH, LLC
741 BOSTON POST ROAD, SUITE 201
GUILFORD, CT
USA 06437

Manufacturing Facility

Defibtech Branford
14 Commercial St
Branford, CT
USA 06405

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

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Branford, CT
USA 06405

Name of Product(s)

AUTOMATED EXTERNAL DEFIBRILLATOR (AED)
DDU-100E Lifeline Defibrillator AED and related accessories
DDU-100E Lifeline Defibrillator AED
DDU-120E Lifeline AUTO Defibrillator AED and related accessories
DDU-120E Lifeline AUTO Defibrillator AED
DDU-E2200 VIEW AUTO Automatic External Defibrillator
DDU-E2200 VIEW AUTO Automatic External Defibrillator and Accessories
DDU-E2300 Lifeline VIEW Defibrillator AED and related accessories
DDU-E2300 Lifeline VIEW Defibrillator AED
DDU-E2450 Lifeline ECG Defibrillator AED and related accessories
DDU-E2450 Lifeline ECG Defibrillator AED
DBP-2009 Battery Pack
DBP-1400 (Battery Pack)
DBP-2800 (Battery Pack)
DDP-100 (Defibrillation Pads)
DDP-200P (Defibrillation Pads)
DBP-2003 (Battery Pack)
DBP-2013 (Battery Pack)
DDP-2001 (Defibrillation Pads)
DDP-2002 (Defibrillation Pads)
DBC-2001 Battery Pack Charging Stand
AUTOMATED CHEST COMPRESSOR (ACC)
RMU-E1000 Automated Chest Compressor and related accessories
RMU-E1000 Automated Chest Compressor
RPM-1000 (External AC Power Adapter)
RPM-2000 (External AC Power Adapter)
RBP-1000 (Battery Pack)
RMF-1000 (Frame)
RPP-1000 (Patient Interface Pads)
RAC-1600 Defibtech ACC Event Connect
RBC-1000 Charging Stand and Wall Charger

END OF PRODUCT LIST

